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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,513	11/03/2003	Graziano Azzolini	27075/GM/cd	1388
7590 12/01/2005			EXAMINER	
MODIANO & ASSOCIATI			DEAK, LESLIE R	
Via Meravigli, 16			ART UNIT	
MILANO, 20123			PAPER NUMBER	
ITALY			3761	

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/698,513		AZZOLINI, GRAZIANO	
	<b>Examiner</b>		<b>Art Unit</b>	
	Leslie R. Deak		3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/12/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 5-18 and 21-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant claims that the duct comprises two consecutive portions arranged to be crossed by mutually opposite flows. However, it is unclear what type of structure applicant is claiming. The duct recited by applicant comprises empty space, which without additional structural limitations, cannot be arranged. Applicant fails to recite any structural limitations that allow the duct portions to be "arranged" in any particular manner. Therefore, it is impossible to determine the metes and bounds of the claims, since there is no recited structure allowing for the arrangement of the space that comprises the claimed duct.

3. Claims 27-29 are is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 27 recites limitations drawn to the feeder devices of the mixing chamber. However, claim 1, from which claim 27 depends, includes only an inferential reference to the feeder devices, claiming only that the intake ports of the mixing chamber are "connectable to respective feeder devices...." It is unclear whether applicant is

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claiming the feeder devices as a part of the claimed invention, since they are not positively recited as structural components of the device claimed in Claim 1.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 5-8, 15-16, 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by US 3,677,248 to McPhee.

McPhee, in the specification and the figures, discloses the device as claimed. In particular, McPhee discloses an air trap chamber or mixing chamber 25 with at least 2 intake ports (see FIGS 1, 3), a hollow body defined by cylindrical wall 32, defining a duct, and an outlet or drain port 33. McPhee illustrates that the intake ports and drain port are connected to chambers and tubes which act as feeder devices and an outflow device as claimed. McPhee further discloses that an embodiment of the mixing chamber 25 comprises an air vent with a check valve 42 that allows gas trapped in the chamber to be vented outside the chamber through a hydrophobic filter 43 (see column 4, lines 45-47).

For the purposes of examination, Examiner has interpreted the consecutive portions of the duct recited in claim 5 (absent any structural limitation that divides the empty space that comprises the duct, as explained above) to be simply the upper and lower portions of the open space defined by walls 32. With

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regard to claims 5-8, 15-16, and 21, the upper portion of the duct disclosed by McPhee is associated with the inlet portion; and a lower portion associated with the outlet. The duct is continuous, connecting the inlet, outlet, and gas vent in a single connected area. Without any structural features dividing the duct, the flow through the duct may be directed to ascend, descend, or flow in any direction desired by the operator depending on the arrangement of the flow into and out of the mixing chamber.

With regard to claim 18 drawn to the position of the valve, such a limitation is held to be a statement of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 9, are rejected under 35 U.S.C. 103(a) as being unpatentable over US 3,677,248 to McPhee.

McPhee, in the specification and the figures, discloses the device substantially as claimed. However, McPhee fails to disclose the claimed locations of the inlet and outlet ports and the gas vent. It would have been obvious to one

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having ordinary skill in the art at the time the invention was made to rearrange the inlet and outlet ports as claimed by applicant, since it has been held that rearranging parts of an invention involves only routine skill in the art. See MPEP 2144.04.

8. Claims 4 and 22-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 3,677,248 to McPhee as applied above, in view of US 5,569,181 to Heilman et al.

McPhee, in the specification and the figures, discloses the device substantially as claimed. However, McPhee fails to disclose that the duct comprises a helical portion. However, Heilman discloses a fluid mixing system with at least two fluid flows that meet at static mixer 20 comprising coaxial helical vanes with channels therebetween that are designed to mix fluids of varying viscosities (see column 3, lines 45-67, FIG 2). The vanes act as a stationary impeller that agitates the fluid and moves it through the chamber.

With regard to claims 27-29, Examiner is assuming that applicant intends to claim the feeder devices inferentially included in claim 1 in order to examine the claims on the merits. McPhee discloses that the inflow and the outflow member comprise valves 26, 27, 28, 29, 47 (see FIG 1) that may meter fluid flow into and out of the mixing chamber. However, McPhee fails to disclose that the valves comprise three-way valves. Heilman discloses that his fluid flow circuit may comprise a three-way stopcock valve that provides fluid flow through the tubing, with a third passage being provided for aspiration or injection of fluids through a syringe or chamber (see column 4, lines 47-55). Therefore, it would

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have been obvious to one having ordinary skill in the art at the time of invention to substitute a three-way stopcock valve as disclosed by Heilman for the valves disclosed by McPhee in order to allow for removal or addition of fluid through the third fluid opening in the valve, as taught by Heilman.

9. Claims 10-13 are is rejected under 35 U.S.C. 103(a) as being unpatentable over US 3,677,248 to McPhee as applied above, in view of US 5,823,987 to Elgas et al.

McPhee, in the specification and the figures, discloses the device substantially as claimed. However, McPhee fails to disclose that the chamber comprises coaxial cylindrical elements in the body of the mixing chamber. Elgas discloses a blood oxygenator and heat exchanger that allows for the mixing of blood with oxygen in chamber 28. Blood is introduced to a cylindrical housing 12 via inlet 30, passed up and over cylindrical insert or manifold 24, and down through the chamber, mixing with oxygen (flowing through helically wound fibers 48 in order to provide some agitation of the blood through the fibers) and flowing out of outlet 32 (see FIG 4). The manifold and flow pattern are designed to provide the maximum amount of mixing surface are while minimizing the overall size and volume of the housing 12 (see column 2, lines 14-25). With regard to claim 13 drawn to a second cylindrical element, it has been held that the duplication of the essential working parts of a device involves only routine skill in the art. See MPEP 2144.04. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a coaxial manifold with complementary helical flow directing elements as disclosed by

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Elgas to the mixing chamber disclosed by McPhee in order to maximize the internal surface area of the mixing chamber without increasing the size or volume thereof, as taught by Elgas.

10. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 3,677,248 to McPhee as applied above, in view of US 3,042,038 to Beacham.

McPhee, in the specification and the figures, discloses the device substantially as claimed. However, McPhee fails to disclose that the air vent may be closed by a float valve. Beacham discloses a drip chamber 4 with an inlet and outlet for fluid flow therebetween through duct or chamber 13. The chamber comprises an air vent 7 that is controlled by a float valve 15 that prevents fluid from escaping the chamber 13 via the air vent (see column 1, lines 45-51). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the air vent check valve disclosed by McPhee with the float valve disclosed by Beacham in order to prevent fluid escape through the air vent, as taught by Beacham.

### ***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. US 4,053,141 Gussfeld
  - i. Static mixer
- b. US 4,522,504 Greverath
  - ii. Inline mixing apparatus



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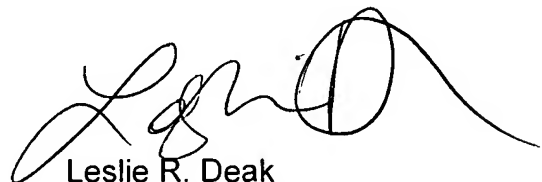
c. US 5,487,606 Keller

iii. Mixing spirals

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leslie R. Deak  
Patent Examiner  
Art Unit 3761  
21 November 2005